

Message Text

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PAGE 01 STATE 139965
ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-07 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: BLONG
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EA/J:EFEATHERSTONE(INFO)

-----054797 021902Z /75

R 021840Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO

UNCLAS STATE 139965

E.O. 11652: N/A

TAGS: OGEN, OTRA, ETRD, EIND, TBIO, JA

SUBJECT: FDA REPRESENTATIVE PROVIDING TECHNICAL AND CON-
SULTATIVE ASSISTANCE TO JAPANESE PHARMACEUTICAL MANUFACTUR-
ERS.

1. FDA ADVISES THAT MR. WILLIAM ZUBER OF THE SEATTLE
DISTRICT OFFICE, WILL BE IN JAPAN JULY 8-AUGUST 7, 1978.
2. MR. ZUBER WILL VISIT 7 PHARMACEUTICAL FIRMS TO
DETERMINE IF THEIR FACILITIES AND OPERATIONS ARE IN ACC-
ORDANCE WITH CURRENT GOOD MANUFACTURING PRACTICES AND
WILL REPORT IF ANY SIGNIFICANT DEVIATIONS ARE NOTED WHICH
WOULD HAVE AN ADVERSE EFFECT UPO' THE SAFETY AND/OR
EFFICACY OF DRUGS THEY MAY IMPORT INTO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:
JULY 7 - DEPART WASHINGTON, DC FOR TOKYO, JAPAN
JULY 10-12 - VISIT HIKARI CHEMICAL INDUSTRIAL CO.
JULY 12 - TRAVEL TOKYO TO OSAKA
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JULY 13-15 - VISIT YOSHITOMI PHARMACEUTICAL INDUSTRIES
JULY 17-19 - VISIT TAKEDA
JULY 19 - TRAVEL OSAKA TO TOKYO
JULY 20-21 - VISIT KYUSHU UNIVERSITY/FUKUORU TO PERFORM

ON SITE GOOD LABORATORY PRACTICE RECORDS REVIEW OF
STAPHAGE LYSATE

JULY 31 - AUGUST 2 - VISIT SANKO CO. LTD.

AUGUST 3-4 - VISIT NIPPON SODA

AUGUST 7 - DEPART TOKYO, JAPAN FOR UNITED STATES.

4. ASSISTANCE OF EMBASSY WILL NOT BE REQUIRED. CHRISTOPHER

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Message Attributes

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Disposition Approved on Date:
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Disposition Event:
Disposition History: n/a
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Disposition Remarks:
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TAGS: OGEN, OTRA, ETRD, EIND, TBIO, JA
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